PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 71043-75037	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/SE2004/000848	International filing date *(day/month/year)* 02.06.2004	Priority date *(day/month/year)* 10.06.2003
International Patent Classification (IPC) or national classification and IPC A61L15/22, A61L24/04, A61F5/445, A61F13/02		
Applicant Mölnlycke Health Care AB et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:

   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:

      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand 10.12.2004	Date of completion of this report 22.09.2005
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Ingrid Falk/EK Telephone No. +46 8 782 25 00

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/000848

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☐ the international application as originally filed/furnished

☒ the description:

pages 1-23 as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☒ the claims:

pages _____ as originally filed/furnished
pages* _____ as amended (together with any statement) under Article 19
pages* 1-4 received by this Authority on 21.07.2005
pages* _____ received by this Authority on _____

☒ the drawings:

pages 1/2-2/2 as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to the sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/000848

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-23	YES
	Claims		NO
Inventive step (IS)	Claims	1-23	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-23	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Documents cited in the International Search Report:
D1: WO 0074738 A1
D2: US 4791149 A

The cited documents represent the general state of the art. The invention defined in claims 1- 23 is not disclosed by any of these documents.
The cited prior art does not give any indication that would lead a person skilled in the art to the claimed skin protection composition, the method for applying a protective layer to the skin and the use of the skin protective composition. Therefore, the claimed invention is not obvious to a person skilled in the art.
Accordingly, the invention defined in claims 1- 23 is novel and is considered to involve an inventive step. The invention is industrially applicable.

Patent claims

1. A skin protection composition characterized in that it comprises a silicone composition which is highly viscous on application and which, after application, cures, by means of crosslinking, to form a soft and skin-friendly elastomer which adheres to the skin and after curing has an adherence to the skin of 0.3-3.0 N/25 mm.

2. A composition as claimed in claim 1, characterized in that, on application, it has a viscosity of 5-300 Pa*s, preferably 10-120 Pa*s, more preferably 20-80 Pa*s, and, after curing, has a penetration (softness) of 2-15 mm, preferably 3-10 mm.

3. A composition as claimed in claim 1 or 2, characterized in that the curing time after application is 0.5 min-24 hrs, preferably 1 min-1 hr, more preferably 1-5 min.

4. A composition as claimed in claim 1, 2, or 3, characterized in that the preparation is hydrophobic.

5. A composition as claimed in one of claims 1-4, characterized in that the silicone composition consists of an addition-curing RTV silicone system.

6. A composition as claimed in claim 5, characterized in that the crosslinkable substance in the silicone system consists of polydimethylsiloxane having some of its methyl groups replaced with vinyl groups and the crosslinking-forming substance consists of dimethysiloxane having some of its methyl groups replaced with hydrogen, and a platinum-based

catalyst.

7. A composition as claimed in claim 5 or 6, characterized in that one or more skin-care substance(s) has/have been added to the silicone composition.

8. A method for applying a protective layer to the skin (stratum corneum), characterized in that a preparation comprising a silicone composition, which is highly viscous on application and which, after application, cures, by means of crosslinking, to form a soft and skin-friendly elastomer which adheres to the skin, is applied to the skin, after which the preparation is allowed to cure to form a soft, skin-friendly elastomer which adheres to the skin.

9. The method as claimed in claim 8, characterized in that the preparation is applied at a layer thickness of 0.1-5 mm.

10. The method as claimed in claim 8 or 9, characterized in that an article for medical use, such as a stoma bag, a tube or parts of a wound dressing or a bandage, is applied to the upper side of the preparation, i.e. that side which faces away from the skin, before the preparation has cured, with the article being affixed to the preparation after the latter has cured.

11. The method as claimed in claim 10, characterized in that the preparation is applied to the article for medical use before it is applied to the skin concurrently with the article.

12. The method as claimed in claim 10 or 11, characterized in that the preparation is designed such that its adherence to the article for medical use is greater than its adherence to the skin after curing.

13. The method as claimed in one of claims 8-12, characterized in that the preparation is applied around a wound, immediately outside the edge of the wound, with a width of 2-100 mm.

14. The method as claimed in claim 13, characterized in that one or more wound dressing(s) is/are applied such that the dressing(s) cover(s) the wound and the area to which the preparation has been applied, with the dressing(s) being applied before the preparation has cured.

15. The method as claimed in claim 14, characterized in that the wound dressing(s) consist(s) of (a) liquid-tight dressing(s).

16. Use of a preparation comprising a silicone composition which is highly viscous on application and which, after application, cures, by means of crosslinking, to form a soft and skin-friendly elastomer which is adhered to skin, for protection of skin (stratum corneum).

17. Use according to claim 16, wherein the preparation on application has a viscosity of 5-300 Pa*s, preferably 10-120 Pa*s, more preferably 20-80 Pa*s, and, after curing, has a penetration (softness) of 2-15 mm, preferably 3-10 mm.

18. Use according to claim 16 or 17, wherein the

preparation after curing on the skin has an adherence to the skin of 0.3-3.0 N/25 mm.

19. Use according to claim 16, 17 or 18, wherein the curing time after application is 0.5 min-24 hrs, preferably 1 min-1 hr, more preferably 1-5 min.

20. Use according to one of claims 16-19, wherein the preparation is hydrophobic.

21. Use according to one of claims 16-20, wherein the silicone composition consists of an addition-curing RTV silicone system.

22. Use according to claim 21, wherein the crosslinkable substance in the silicone system consists of polydimethylsiloxane having some of its methyl groups replaced with vinyl groups and the crosslinking-forming substance consists of dimethysiloxane having some of its methyl groups replaced with hydrogen, and a platinum-based catalyst.

23. A preparation as claimed in one of claims 16-22, wherein one or more skin-care substance(s) has/have been added to the silicone composition.